IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327** **JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO ALL PLAINTIFFS LISTED IN EXHIBIT "A" TO THE INITIAL MOTION	

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR *DAUBERT* MOTION TO EXCLUDE FDA EXPERT TIMOTHY ULATOWSKI

The primary points in Plaintiffs' *Daubert* motion against Timothy Ulatowski were to demonstrate that almost all of his opinions are regulatory in nature, and to show that he has no expertise to give any opinions that might arguably fall outside of the regulatory context—i.e., opinions about the strength of Ethicon's warnings, the quality of its patient education materials, or the safety of its manufacturing practices.

Very little of Defendants' response contradicts those points. While Defendants have explained why his opinions were offered, nothing about Defendants' arguments suggests that the opinions are anything other than regulatory opinions. Defendants make a cursory argument about qualifications, but they do not really contest the assertion that Mr. Ulatowski has no expertise outside of the regulatory context. For these reasons, his opinions should be entirely excluded, if the Court takes the same position it has previously taken with regard to the admissibility of FDA evidence.

To some degree, this motion sets up a game of shadow boxing at this stage. Most of Plaintiffs' motion is based on relevance, or probative value as compared with the Rule 403 risks, and those issues will be determined in large part by the Court's future order on the admissibility of FDA evidence. Plaintiffs did not take a position on what the scope of the Court's future FDA order **should** be. Rather, Plaintiffs started with the premise that the Court would follow the same path that it followed in the *Bellew* case. In that case, the Court wrote that "this court will not tolerate the presentation of evidence that touches on or in any way alludes to the 510(k) clearance process." *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 6680356, at *10 (S.D. W. Va. Nov. 25, 2014). The Court continued: "Furthermore, insofar as Mr. Ulatowski's opinions relate to FDA regulations or procedures, FDA decision-making, FDA communications, or Ethicon's compliance with such, they are **EXCLUDED.** I have previously expressed concern with the risks of leading the jury into the confusing domain of the FDA." *Id.* Plaintiffs' memorandum then explained, point by point, why each of Mr. Ulatowski's opinions presents the problems that the Court sought to avoid in *Bellew*.

Motions *in limine* are due June 15, and Plaintiffs will file a motion on FDA evidence. Both sides will express where they believe the admissibility line ought to be drawn, and this Court will of course have the final say. Plaintiffs have proffered experts Peggy Pence[1] and Suzanne Parisian to give regulatory opinions—in addition to other opinions—because of the uncertainty as to how the Court would rule on FDA exclusion for Wave 1. As to some of Mr. Ulatowski's opinions, Defendants argue that they are purely "defensive," and will only be given if Plaintiffs are permitted to give a particular opinion. Generally speaking, Plaintiffs do not

[1] In contrast to Mr. Ulatowski, this Court has previously allowed Dr. Pence to give opinions because she has relevant opinions, which she is qualified to give, that are not based predominantly on regulatory matters. *See Sanchez v. Boston Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *34 (S.D. W. Va. Sept. 29, 2014) (allowing Dr. Pence's opinions as to pre-market testing).

disagree with that position. But by Defendants' own admission, such opinions only become relevant—and therefore admissible—if the Court allows the Plaintiffs' experts to give the regulatory opinion in question.

To the extent that Defendants' brief is devoted to supporting the admission of FDA evidence generally, the Court has addressed and rejected Defendants' arguments in one way or another. *See, e.g.*, *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014) ("That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law."); *see also Bellew*, *supra*. In *Lewis*, this Court also noted that "Ethicon itself has recognized the importance of viewing the TVT as a whole, rather than just its component parts." *Lewis*, 991 F. Supp. 2d at 760. Thus, the argument that the FDA's approval of Prolene is relevant information about the safety of the TVT devices has no merit. In addition, this Court has strongly rejected prior assertions by Defendants that *Medtronic v. Lohr*, 518 U.S. 470 (1996), is somehow distinguishable on the issue of whether the 510(k) process establishes the safety and efficacy of the device. *Mullins v. Ethicon, Inc.*, No. 2:12-CV-02952, 2015 WL 7761033, at *1 (S.D. W. Va. Dec. 2, 2015) ("In *Lohr*, the Court held that the 510(k) clearance process—which is rooted in a determination of 'substantial equivalence' rather than safety and effectiveness—does not preempt state-law design defect claims.").[2]

To the extent that further argument on those general points is necessary, Plaintiffs will address those issues in their motion *in limine*. In the remainder of this brief, Plaintiffs will address several of the point-by-point responses issued by the Defendants—again using the TVT-O report as a representative sample of Mr. Ulatowski's opinions.[3] The numbers skipped below

[2] In both *Lewis* and *Mullins*, this court rejected preemption arguments that raised similar points to the arguments Defendants are now making in support of the alleged relevance of FDA evidence.

[3] Defendants basically accepted the TVT-O Report as being representative of all of Mr. Ulatowski's opinions. They gave one additional example, stating that if Dr. Pence is able to opine about the marketing

all relate to opinions that Defendants have stated they will not offer unless Plaintiffs are permitted to offer certain evidence.

2) **Assertion: Prolene is supported by the FDA as safe and effective:** Defendants argue that this opinion does not implicate the 510(k) process, which raises two points. First, Defendants have characterized the Court's prior rulings as excluding only evidence about the 510(k) process. (Def. Resp. at 1). In reality, the Court—while speaking about Mr. Ulatowski specifically—excluded all opinions related to "FDA regulations or procedures, FDA decision-making, FDA communications, or Ethicon's compliance with such … ." *Bellew*, 2014 WL 6680356, at *10. Second, even if the Court does limit its exclusions to the 510(k) process this time, the opinion about Prolene should be excluded. If Defendants are permitted to argue that FDA approval of Prolene constitutes evidence of the safety of the TVT-O, then Plaintiffs will be forced to explain that the device as a whole has not been approved by the FDA—thereby necessitating discussion of the 510(k) process and what it entails.

3) **Assertion: Changing the TVT-O would require a new 510(k) clearance**: This Court soundly rejected the argument that Plaintiffs' claims are preempted because changing the TVT would require additional 510(k) clearance. *See Mullins*, 2015 WL 7761033, at *3 ("Congress, the Supreme Court, and common sense counsel against such a result."). Because the 510(k) process is not a substantial barrier to a new design, it is also not an impediment that would prevent an alternative design from being "available," as Defendants claim. And allowing such an argument would necessitate a mini-trial about the 510(k) process—something this Court has clearly sought to avoid in prior cases.

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of Prolift without FDA clearance, then Mr. Ulatowski's opinions on that subject would be relevant. (Def. Resp. at 1-2). Plaintiffs acknowledge that if Dr. Pence is able to give this opinion about Prolift, then Mr. Ulatowski's counter-argument would be relevant.

4) **Assertion: There is no reason for the FDA to recommend labeling changes for the TVT-O:** The Court has repeatedly rejected the notion that the 510(k) process involves safety. Thus, the Court should have little trouble rejecting Defendants' argument that "'clearance' signifies *safety*." (Def. Resp. at 9). In addition, Defendants draw a distinction between Class II and Class III devices. Having to explain such a distinction to the jury would be time consuming and confusing. Ultimately, what the FDA has or has not recommended about the label has no bearing on whether the label has been safe under state law.

5) **Assertion: FDA pronouncements on patient brochures:** To the extent that Plaintiffs are permitted to base a failure-to-warn claim[4] on the absence of information in patient education materials, Mr. Ulatowski's (incorrect) opinion that the FDA does require risk information in patient brochures may have limited relevance. Otherwise, it is completely irrelevant.

7) **Assertion: The TVT-O was adequately manufactured:** Defendants have presented no evidence or argument supporting Mr. Ulatowski's expertise to opine about manufacturing defects. Even if certain FDA documents are relevant to that issue, Mr. Ulatowski has no expertise on the subject matter, so he would just be a person reading those FDA documents. Defendants try to exclude such narrative testimony in basically every *Daubert* motion they file.

10) **Assertion: Ethicon met pre-market requirements with the TVT-O**: Defendants characterize the opinion as "defensive," to be offered only if Plaintiffs offer evidence that "Ethicon failed to conduct proper testing before marketing TVT-O or otherwise did not

[4] This limited concession applies only to a failure-to-warn claim. To the extent that a plaintiff may bring a separate claim based on a negligent or fraudulent misrepresentation in patient education materials, Dr. Ulatowski's opinion is irrelevant. Such claims are not based on a duty to warn; rather, they are based on the theory that if the Defendants choose to make statements to patients about their product, they have a duty under state law to speak truthfully.

comply with FDA 510(k) requirements." (Def. Resp. at 11). Those are two very different issues that Defendants are trying to lump together.

Plaintiffs have no plans to make assertions about which 510(k) requirements were not met. However, Plaintiffs will put forth evidence that Ethicon's pre-market testing was inadequate. This issue is distinct from the FDA, as evidenced by the Court's allowing Dr. Pence to give such testimony. *Sanchez v. Boston Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *34 (S.D. W. Va. Sept. 29, 2014). Defendants try to save Mr. Ulatowski's opinion on pre-market testing by saying that it focused on "industry standards." (Def. Resp. at 11-12). However, it is clear from his report that his perspective is one of FDA compliance. His report states, in a subheading, that "[t]he TVT-O 510(k) submission meets FDA requirements, industry standards and best practices."[5] The opinion refers to Ethicon's compliance with FDA regulations throughout.[6] Generally, the opinion is focused on following certain procedures; it says nothing about whether Ethicon's pre-market testing actually supported the alleged safety of the TVT-O device.

11) Defendants are correct that a principal question in the litigation relates to the adequacy of Ethicon's warnings. Where Defendants are wrong, however, is in asserting that the question is determined by compliance with FDA standards—or lack thereof. The issue will be determined by a given state's requirements for warnings. Thus, testimony about FDA compliance has limited relevance, if any, and it creates the additional problem of suggesting the

[5] TVT-O Report, Exhibit D to Pl. Motion, at p. 76.
[6] *See id.* at 77 ("The information meets the regulatory requirements."); *id.* at 78 ("FDA has full access to all the design control documents used as the basis for the marketing of a device and for a Special 510(k)."); *id.* at 79 ("According to FDA regulations, a DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of the quality system regulation.").

FDA has approved the device. Meanwhile, Mr. Ulatowski has no expertise to opine about whether the warnings are substantively sufficient, as he has admitted.[7]

13) **Assertion: The 510(k) review includes an analysis of the safety and effectiveness of the device**: Defendants' argument essentially rehashes their general argument as to why 510(k) evidence is supposedly relevant. The classification makes no difference. This Court has stated numerous times that the 510(k) process has nothing to do with safety and efficacy. *See, e.g.*, *Lewis*, 991 F. Supp. 2d at 752 ("The Supreme Court has determined that the 510(k) process is focused on equivalence with a preexisting device rather than safety, while the premarket approval process is focused on safety and efficacy."). The Court should not change its stance now—a stance supported by the U.S. Supreme Court—just because Defendants have come up with yet another spin on this failed argument.

CONCLUSION

Mr. Ulatowski has no expertise outside of regulatory matters, and this Court has consistently excluded regulatory evidence. If the Court takes the same approach to regulatory evidence for the Wave 1 cases, then Mr. Ulatowski should be excluded entirely from testifying.

Dated: May 16, 2016

[7] *See* Pl. Memo. in Support at 14, citing Ulatowski Dep., Ex. H, at 144:6-20.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on May 16, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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